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INTERNATIONAL APP. NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/EP2004/006426 14 June 2004 16 June 2003

TITLE OF INVENTION
POLYANIONIC POLYMER ADJUVANTS FOR HAEMOPHILUS INFLUENZA B
SACCHARIDE VACCINES

APPLICANT(S) FOR DO/US
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WAUTERS

FILING OF AN INFORMATION DISCLOSURE STATEMENT

Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

- [X] A copy of the International Search Report, which issued on International Application No.

 PCT/EP2004/006426 is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.
- [] Copies of references not listed on the International Search Report are enclosed.

The attached list of citations on PTO Form 1449 is being submitted under the provisions of 37 CFR §1.56 and §1.97 in order to comply with the duty of disclosure. Their inclusion herein should not, however, be construed as an admission that any particular cited reference is effective prior art or that it discloses or renders obvious any aspect of the claimed invention. This statement is being filed within the time period specified in 37 CFR §1.97(b). No fee is required.

Respectfully submitted,

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Form PTO-1449 U.S. Department of Commerce ATTY, DOCKET NO. INTERNATIONAL APPLICATION NO. PCT/EP2004/006426 Patent and Trademark Office VB60298 INFORMATION DISCLOSURE STATEMENT **APPLICANT** Garcon et al. BY APPLICANT GROUP FILING DATE Herewith Not Yet Assigned (Use several sheets if necessary) **U.S. PATENT DOCUMENTS** Class Subclass Filing Date **Document Number** Date Examiner Name If Appropriate Initial **FOREIGN PATENT DOCUMENTS Document Number** Date Country Class **Subclass Translation** Yes WO 98/17310 4/30/98 **PCT PCT** WO 02/00249 1/3/02 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Gupta et al., "Biodegradable Polymer Microspheres as Vaccine Adjuvants and Delivery Systems". Developments in Biological Standardization, 92: 63-78 (1998). Boehm-Gerard et al., "On Technological and Immunological Benefits of Multivalent Single-Injection Microsphere Vaccines". Pharmaceutical Research, 19(9): 1330-1336 (2002). Raghuvanshi et al., "Improved Immune Response from Biodegradable Polymer Particles Entrapping Tetanus Toxoid by use of Different Immunization Protocol and Adjuvants". Int'l. J. Pharmaceutics, <u>245(1-2)</u>: 109-121 (2002). Peyre et al., "An Experimental Divalent Vaccine Based on Biodegradable Microspheres induces Protective Immunity Against Tetanus and Diphtheria". J. Pharm. Sci., 92(5): 857-966 (2003). Gupta et al., "Evaluation of a Guinea Pig Model to Assess Interference in the Immunogenicity of Different Components of a Combination Vaccine Comprising Diphtheria, Tetanus and Acellular Pertussis (DTaP) Vaccine and Haemophilus Influenzae Type B Capsular Polysaccharide Conjugate Vaccine". Biologicals, 27(2): 167-176 (1999). Richard et al., "Production and Mass Transfer Characteristics of Non-Newtonian Biopolymers for Biomedical Applications". CRC Critical Rev. in Biotechnol., 22(4): 355-374 (2002). Nichol et al., "Poly-L-glutamage, an Anionic Polymer, Enhances Transgene Expression for Plasmids Delivered by Intramuscular Injection with in vivo Electroporation". Gene Ther., 9(20): 1351-1358 (2002).Milas et al., "Poly(L-glutamic acid)-Paclitaxel Conjugate is a Potent Enhancer of Tumor Radiocurability". Int'l. J. Radiation Oncol. Biol. Phys., 55(3): 707-712 (2003). DATE CONSIDERED **EXAMINER** asl ·EXAMINER: Initial if of tation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not

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Sheet 2 of 2 . INTERNATIONAL APPLICATION NO. Form PTO-1449 U.S. Department of Commerce ATTY, DOCKET NO. PCT/EP2004/006426 Patent and Trademark Office VB60298 INFORMATION DISCLOSURE STATEMENT **APPLICANT** Garcon et al. **BY APPLICANT** FILING DATE **GROUP** Not Yet Assigned Herewith (Use several sheets if necessary) **U.S. PATENT DOCUMENTS Subclass** Filing Date Class **Document Number** Date Name Examiner If Appropriate Initial **FOREIGN PATENT DOCUMENTS** Subclass **Document Number Date** Country Class **Translation** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Yang et al., "Poly(glutamic acid) Poly(ethylene glycol) Hydrogels Prepared by Photoinduced Polymerization: Synthesis, Characterization, and Preliminary Release Studies of Protein Drugs". J. Biomed. Materials Res., 62(1): 14-21 (2002). Diwan et al., "Enhancement of Immune Responses by Co-Delivery of a CpG Oligodeoxynucleotide and Tetanus Toxoid in Biodegradable Nanospheres". J. Controlled Rel., 85(1-3): 247-262 (2002). Sanchez et al., "Formulation Strategies for the Stabilization of Tetanus Toxoid in Poly(lactide-coglycolide) Microspheres". Int'l.J. Pharmaceutics., 185(2): 255-266 (1999). Esparza et al., "Parameters Affecting the Immunogenicity of Microencapsulated Tetanus Toxoid". Vaccine, 10(10): 714-719 (1992). GlaxoSmithKline NZ Ltd. "Datasheet - Hiberix". New Zealand and Medical Devices Safety Authority, 'Online! 2002, XP002306401. Jiang et al., "Stabilization of a Model Formalinized Protein Antigen Encapsulated in Poly(lactide-coglycolide)-based Microspheres". J. Pharm. Sci., 90(10): 1558-1569 (2001). DATE CONSIDERED **EXAMINER** ·EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and noticonsidered. Include copy of this form with next communication to applicant.